



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Food and Drug Administration
1401 Rockville Pike
Rockville MD 20852-1448

Our STN: BL 103821/5020

January 31, 2002

Lallan Giri, Ph.D.
BioPort Corporation
3500 N. Martin Luther King Jr. Blvd.
Lansing, MI 48906

Dear Dr. Giri:

Your request to supplement your biologics license application to include Hollister-Stier Laboratories LLC, Spokane, Washington, as a contract manufacturer for the filling of Anthrax Vaccine Adsorbed (AVA) has been approved.

Under this approval, lots of AVA filled at Hollister-Stier Laboratories LLC shall have an expiration dating period of 18 months from the date of manufacture when stored at 2-8 °C. Any requests to extend the dating period beyond 18 months will require the submission of supporting data as a supplement to your biologics license application for review and approval.

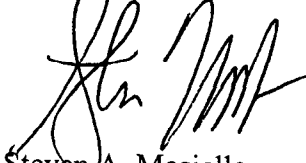
We acknowledge your written commitments, as stated in your letter of January 17, 2002, to provide the following additional information post-approval:

1. Real time stability data on final containers for the consistency lots, FAV063, FAV064 and FAV065, will be accumulated at the following intervals: 6, 9, 12, and 18 months, and these stability data will be provided to CBER as they become available.
2. BioPort has committed to place a minimum of two filled lots of AVA on stability each year.
3. To perform a suitable extraction study for the West Stoppers using the diluent of the Anthrax Vaccine Adsorbed. The study will be completed by July 2002 and the results submitted to CBER in the next annual report.

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The information contained in the above-referenced supplement will be included in your biologics license application file.

Sincerely,

A handwritten signature in black ink, appearing to read 'S. Masiello', written over a horizontal line.

Steven A. Masiello

Director

Office of Compliance and Biologics Quality

Center for Biologics Evaluation and Research